

REMARKS

1. This paper is responsive to the non-final Office Action mailed on February 26, 2008. Claims 1 to 30 are pending in this application and have been rejected. Applicants believe that no fee is due in connection with this Response, however, please charge Deposit Account No. 02-1818 for any fee deemed owed.

2. Claims 1-30 are rejected for double patenting in view of co-owned U.S. Pat. 7,208,092, and are also provisionally rejected for double patenting in view of copending and co-owned U.S. Pat. Appl. 10/623,316. The rejection states that terminal disclaimers, enclosed, will overcome the double patenting rejections. The Examiner is requested to withdraw the rejections in view of the enclosed terminal disclaimers.

3. Claims 1-2 and 5-12 are rejected under 35 U.S.C. §103 (a) as being unpatentable in view of U.S. Pat. No. 6,254,567 to Dennis Treu et al. ("Treu") in view of Roberts et al., "Innovative Peritoneal Dialysis Flow-Thru and Dialysate Regeneration" ("Roberts"). Claims 13, 14, 16-18, 20, 22 and 23 are also rejected under 35 U.S.C. §103 (a) as being obvious in view of Treu and Roberts. Claims 24-30 are also rejected under 35 U.S.C. §103 (a) as being unpatentable in view of Treu and Roberts, and Claims 3, 4, 19, and 21 are rejected under 35 U.S.C. §103 (a) as being unpatentable in view Roberts only. No prior art rejection is cited for Claim 15, which is therefore allowable under 35 U.S.C. §102, since no reason for its non-patentability has been otherwise advanced.

4. Claims 1-2 and 5-12 are rejected under 35 U.S.C. §103 (a) as being unpatentable in view of U.S. Pat. No. 6,254,567 to Dennis Treu et al. ("Treu") in view of Roberts et al., "Innovative Peritoneal Dialysis Flow-Thru and Dialysate Regeneration" ("Roberts"). Claim 1 recites "a catheter having an inflow lumen and an outflow lumen" as part of the claimed system. The rejection cites Treu, Fig. 2, as teaching this limitation. As seen in Fig. 2 of Treu, and as described in the text, col. 6, lines 47-52, Treu teaches only a single access through a single indwelling catheter, which provides semi-continuous flow of dialysis solution into and out of the peritoneal cavity in a succession of draw modes and return modes.

This disclosure is in complete contrast to both the claims and the teachings of the present application, which explains the benefits of a continuous flow of peritoneal dialysis into and out of the patient's peritoneum. Even if Treu disclosed a double-lumen catheter (inflow lumen and outflow lumen), Treu in fact teaches against a double-lumen catheter, as seen in Figs. 3 and 4, and the accompanying text at col. 7, lines 27-32. Treu teaches specifically that the device of Figs. 3-4 provides single access if one device is used, and dual access if two devices are used. Treu's devices have been specially designed to sustain high flow rates for peritoneal dialysis and to give positive pinching action to close the internal valve. See col. 7, line 33 to col. 8, line 48. Thus, Treu, in combination with Roberts, does not teach or suggest all the limitations of Claim 1, which is therefore allowable. Dependent Claims 2 and 5-12 are allowable at least because Claim 1 is allowable. The Examiner is therefore respectfully requested to withdraw the rejection of Claims 1-12.

In addition, numerous of the dependent claims are also not taught or suggested in the references. For example, Claim 9 recites that the initial volume of dialysate is circulated along the fluid loop during an initial period without the continuous feed of the additional volume of the dialysate into the fluid loop and the continuous discharge of dialysate from the fluid loop. The cited example from Roberts, p. 377, col. 1, paragraph 1, teaches just the opposite, that the fresh dialysate is used for inflow and that the outflow is adjusted for the inflow. Accordingly, the references do not teach the limitations of Claim 9, which is therefore allowable.

Claim 12 recites that the feed rate and discharge rate are varied to create tidal CFPD. As Applicants understand it, tidal CFPD, also known as TPD, occurs when the inflow and outflow are varied, but a constant reserve volume of dialysate remains within the peritoneal space throughout the treatment, and a tidal volume is exchanged with each cycle. See, e.g., *Tidal peritoneal dialysis: comparison of different tidal regimens and automated peritoneal dialysis*, Peter H. Juergensen et al., Kidney Int., vol. 57 (2000), pp. 2603-2607; *A comparison of clearances on tidal peritoneal dialysis and intermittent peritoneal dialysis*, Peritoneal Dialysis Int., vol. 14 (1994), pp. 145-148. The citation from Roberts, p. 377, col. 1, paragraph 2, does not mention TPD, tidal CFPD, or the method described herein with a constant volume of dialysate in the peritoneum. Accordingly, Treu and Roberts do not teach or suggest Claim 12.

5. Claims 13, 14, 16-18, 20, 22 and 23 are also rejected under 35 U.S.C. §103 (a) as being obvious in view of Treu and Roberts. Claim 13 recites, among other limitations, a double lumen catheter and “a fluid circuit in fluid communication with the catheter, the fluid circuit consisting of [with additional limitations]” (emphasis added).

As noted above for Claim 1, Treu does not disclose a double-lumen catheter, i.e., a catheter with an inflow lumen and an outflow lumen” because Treu has devised his own access, as seen in Treu’s Figs. 3 and 4. In addition, Treu, in cited Fig. 2, and in other figures of the application, discloses other components, such as pressure sensors P (numerals 76, 78). These additional limitations violate the “consisting of” limitation of Claim 13. Thus, Treu does not teach or suggest the claimed system for providing peritoneal dialysis of Claim 13. Dependent claims 14, 16-18, 20, 22 and 23 are allowable at least because independent Claim 13 is allowable. The Examiner is respectfully requested to withdraw the rejection of these claims.

6. Claims 24-30 are also rejected under 35 U.S.C. §103 (a) as being unpatentable in view of Treu and Roberts. By the same reasoning used above for Claims 1 and 13, Treu’s teachings are inconsistent with use of a double-lumen catheter. Treu’s invention includes a new, different single-access device, and Treu specifically teaches the use of one of these devices for single access (periodic inflow and outflow) and two such devices if continuous inflow and outflow are desired. Treu thus teaches against a double-lumen catheter as recited in the claims of the present application, and the combination does not teach or suggest Claim 24.

In addition, several of the dependent claims include limitations not taught in either Roberts or Treu. For example, Claim 30 recites a chamber coupled to the fluid loop, and the Office Action cites Treu, chamber 88, as shown in Treu Fig. 2. This same chamber, however, has already been cited as the Claim 24 “supply of dialysate.” See Office Action, p. 4, lines 6-9, and p. 10, line 15 (citing the same “supply of dialysate coupled to the fluid loop.” Since the references must teach or suggest all the limitations of the claims, one by one, the same vessel 88 of True cannot serve as both the “supply of dialysate” and the “chamber.” Accordingly, at least Claims 24 and 30 are not taught or suggested by the references and are allowable. The Examiner is respectfully requested to withdraw the rejections.

7. Claims 3, 4, 19, and 21 are rejected under 35 U.S.C. §103 (a) as being unpatentable in view Roberts only. In order to make out a prima facie rejection, the references must teach or suggest all the limitations of the claims. The Office Action as much as admits that the references do not teach the limitations of these claims by asserting that discovering optimum values, such as the one-half or one-third circulation rates of Claims 3, 4, and 19, involves only routine skill in the art, and by inference, are not patentable. The M.P.E.P. is not cited, by rather *In re Boesch*.

In re Boesch, 205 U.S.P.Q. 215 (C.C.P.A. 1980) concerned a case in which the Applicants claimed ranges of properties that were not commensurate in scope with their disclosure. *Id.* at 220. In the present instance, Applicants have claimed a feed rate/discharge rate that is about equal to one-half the circulation rate (Claim 3) or about equal to one-third the circulation rate (Claim 4). Roberts teaches about 0.18 to about 0.25 times the circulation rate, that is, Roberts teaches away from the claimed rate. See Roberts, p. 377. Using Table 2 and col. 2, one sees a peritoneal flow rate of about 120 ml/min (7200 ml/hr) and an inflow/outflow rate of about 30 ml/hr (1800 ml.hr), one arrives at an inflow/outflow rate that is about 0.25 the circulation rate. Using the 36 ml/min rate for fresh dialysate from Table 1, p. 376, one arrives at an inflow/outflow rate of 2160 ml/hr and a circulation rate of 200 ml/min (12000 ml/hr) of about 0.18.

Thus, while Applicants have disclosed and claimed rates of one-third or one-half the circulation rate, see, e.g., Claims 3 and 4, Roberts teaches substantially lower rates. Accordingly, at least Claims 3 and 4 are not taught or suggested in the prior art, but instead, the prior art teaches against the claimed subject matter. Claims 19 and 21 are allowable at least because they depend from allowable claims.

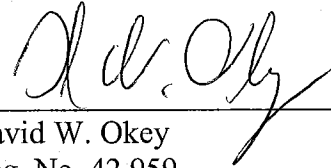
8. Applicants submit that the claims are in condition for allowance, and respectfully request issuance of a Notice of Allowance. If the Examiner believes that a telephone conversation would expedite prosecution in this case, or would be of use to the Examiner, she is

respectfully requested to call the undersigned.

Respectfully submitted,

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